REMARKS

In the Office Action dated July 13, 2007, the Examiner has set forth a requirement for restriction under 35 U.S.C. §121, alleging that the subject matter defined by the claims of the present invention represents the following five separate and distinct inventions:

Group I Claims 1-10 and 12 as drawn to a method of detecting or monitoring the onset of an advanced neoplasm in a mammal comprising screening for the level of inhibin protein in a biological sample, class 435, subclass 4.

Group II Claims 1-10 and 12 as drawn to a method of detecting or monitoring the onset of an advanced neoplasm in a mammal comprising screening for the level of inhibin gene expression of detecting an inhibin polynucleotide in a biological sample, class 435, subclass 4.

Group III Claim 51 and 78 in part, as drawn to a diagnostic kit for assaying biological samples comprising an agent for detecting α-inhibin encoding nucleic acids, class 435, subclass 4.

Group IV Claims 51-54, and 78 as drawn to a diagnostic kit for assaying biological samples comprising an agent for detecting α-inhibin protein. Claim 51 will be examined with this group to the extent that it reads on an agent for detection of α-inhibin protein, class 435, subclass 4.

Group V Claims 55-56, 61-62, 67-75, as drawn to a method of modulating the invasiveness of a neoplastic cell comprising modulating the level of intracellular inhibin protein, whereins aid modulation is up-regulation that induces invasiveness, and method of modulating the invasiveness of a neoplastic cell comprising modulating the level of intracellular inhibin protein, wherein said modulation is down-regulation that inhibits invasiveness, and a method for the treatment and/or prophylaxis of a condition characterized by an advanced neoplasm or a predisposition to the development of a condition characterized by an advanced neoplasm comprising down-regulating inhibin levels, classified in class 424, subclass 130.1.

In order to be fully responsive to the Examiner's requirement for restriction, Applicants provisionally elect to prosecute the subject matter of Group I, Claims 1-10 and 12, as drawn to a method of detecting or monitoring the onset of an advanced neoplasm in a mammal comprising screening for the level of inhibin protein in a biological sample, class 435, subclass 4.

Applicants also provisionally elect prostate as the species for continued prosecution. Applicants reserve the right to file one or more divisional applications directed to the non-elected subject matter in this application in the event that the pending restriction requirement is made final.

In the first instance, Applicants observe that the present application is a U.S. national stage application submitted under 35 U.S.C. § 371. The Examiner alleges that the present application lacks unity of invention. However, the Examiner's restriction requirement appears to apply both the unity of invention practice under PCT Rule 13 and the restriction practice in the U.S. In this regard, Applicants respectfully direct the Examiner's attention to MPEP §1893.03(d), which states "Examiners are reminded that unity of invention (not restriction) practice is applicable . . . in national stage applications submitted under 35 U.S.C. 371." Thus, Applicants will address the present restriction requirement under PCT Rule 13.

Pursuant to 37 C.F.R. §§1.111 and 1.143, Applicants hereby traverse the Examiner's requirement for restriction and request reconsideration thereof in view of the following remarks.

A requirement for restriction presupposes an analysis of the subject application in light of the rules governing this practice, i.e., 37 C.F.R. §1.499 and PCT Rules 13.1 and 13.2. PCT Rule 13.1, first sentence, states: "The international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ('requirement of unity of invention')." (Emphasis added.) PCT Rule 13.2 states: "The expression "technical features' shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art." (Emphasis added.)

The Examiner alleges that the subject matter listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack

the same or corresponding special technical features for the following reasons. The Examiner alleges that WO98/47526 teaches a method of modulating cell growth by administering inhibin or an inhibin antagonists or agent that modulate the expression of inhibin. Therefore, the Examiner reasons that the pending claims in the present application do not include a special technical feature that define a contribution over prior art, and cannot share a special technical feature.

Applicants respectfully submit that unity of invention is the issue at hand. The Examiner should not rely on an evaluation regarding novelty and/or inventive step of the present invention over certain prior art in order to determine whether the requirement of unity of invention is satisfied under PCT Rule 13.1. Applicants should be given the opportunity to argue on merits during prosecution whether the claims involve novelty and/or inventive steps. Restriction of the claims at this stage would deny Applicants such an opportunity.

Moreover, Applicants observe that WO98/47526 was filed in 1998 and claims a priority date of April 23, 1997. Applicants respectfully submit that WO98/47526 was one of the very early patent applications that describe the relationship between inhibin and the onset of cancer. WO98/47526 teaches that a downregulation in the level of inhibin is diagnostic of the onset of cancer. However, Applicants respectfully submit that the present invention is partly predicated upon the recognition that an upregulation in the level of inhibin is indicative of an advanced cancer state. This unique recognition provides the basis for developing methods and products for detection and diagnostic for onset of an advanced neoplasm or method for modulating the invasiveness of a neoplastic cell. It is respectfully submitted that all of the claims presented in the present application share the technical feature of detecting, monitoring and/or modulating an advanced cancer state characterized by an upregulated inhibin level. It is

submitted that the present claims, when considered as a whole, define a contribution over the prior art, and should be examined in the same application.

Applicants respectfully submit that WO98/47526 in fact teaches away or teaches a converse notion from that of the present invention. WO98/47526 does not anticipate the present invention or render the present invention obvious.

Further, it is observed that Group I (Claims 1-10 and 12) is drawn to a method of detecting or monitoring the onset of an advanced neoplasm in a mammal by screening for the level of inhibin protein in a biological sample; and Group II (Claims 1-10 and 12) is drawn to a method of detecting or monitoring the onset of an advanced neoplasm in a mammal by screening for the level of inhibin gene expression in a biological sample. In this regard, Applicants respectfully submit that nucleotide sequences encoding the same protein are not considered to be independent and distinct inventions and will continue to be examined together. See MPEP § 803.04.

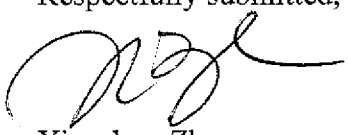
With respect to the species election, Applicants submit that all of the claims of elected Group I (i.e., claims 1-10 and 12), except Claim 12, read on and are generic to the elected species of prostate neoplasm. Applicants acknowledge that upon the allowance of a generic claim, Applicants will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim.

Finally, Applicants respectfully submit that a determination to make the pending restriction requirement final must evidence the patentable distinctness of all defined five groups and species, one from another, as presented by the Examiner.

Accordingly, it is respectfully submitted that Claims 1-10, 12, 51-56, 61-62, 67-75 and 78 satisfy the requirements for unity of invention. Applicants respectfully urge that the

Examiner reconsider and withdraw the requirement for restriction and provide an action on the merits with respect to all the claims, or at least consider Groups I and II together.

Respectfully submitted,



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